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14 January 2003

WATERMARK PATENT & TRADEMARK ATTORNEYS  
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HAWTHORN VIC 3122

Your Ref : P19680AU00

Examiner's first report on patent application no. 30889/00  
by SBL VACCIN AB

Last proposed amendment no.

Dear Madam/Sir,

I am replying to the request for examination. I have based this report on the pamphlet. I have examined the application and I believe that there are lawful grounds of objection to the application. These grounds of objection are:

1. There is no Notice of Entitlement on file. You will need to file one because an application without a Notice of Entitlement cannot be accepted.
2. The invention defined in claims 1-4 is not novel and lack an inventive step when compared with the following document which discloses all the essential features of the invention claimed:

(i) Ahren, C et al (1993) Vaccine, Vol. 11(9):929-934\*

Citation (i) teaches an oral vaccine composition comprising a mixture of cholera B subunit and formalin killed *E. coli* of three different strains; each lacking the LT enterotoxin gene (column 2, paragraph 2), in phosphate-buffered saline. In light of this disclosure, claims 1-4 cannot be considered to be not novel.

3. The invention defined in claims 1-4 do not involve an inventive step when compared to the disclosure of prior art document:

(ii) Savarino, SJ et al (1998) Journal of Infectious Diseases. 177:796-9\*

The citation is directed to a problem similar to the applicant's problem, and in searching the problem a person skilled in the art could reasonably be expected to have found, and to have ascertained, understood, and regarded, this prior art as relevant.

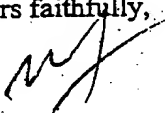
Citation (ii) teaches oral compositions of ETEC/rCTB vaccine (column 2, paragraph 3). The prior art differs from the current invention in the use of a recombinant CTB rather than native CTB. It is noted that the *E. coli* strains selected are LT negative.

Furthermore, appended claims 2-4 relate to parameters which can be arrived at by the application of normal design procedures when the general technical knowledge about the state of the art is used and hence do not contribute to patentable invention.

\*Provided for the applicant's benefit.

You have 21 months from the date of this report to overcome all my objection(s) otherwise your application will lapse. You will need to pay a monthly fee for any response you file after 12 months from the date of this report.

Yours faithfully,



MARIA ONG  
Examiner of Patents, Section B3  
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